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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,795	03/10/2004	Carlos R. Plata-Salaman	ORT-1575CON	4508

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
12/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com
lhowd@its.jnj.com
gsanche@its.jnj.com

Office Action Summary	Application No.	Applicant(s)	
	10/797,795	PLATA-SALAMAN ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,25 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,25 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 12/16/2009, have been fully considered but they are not deemed to be persuasive to support patentability. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-21, 25 and 32 are under examination as far as they read upon the elected species: neurodegenerative disorders associated with an abrupt insult resulting from hypoxia-ischemia (See election of 3/2/2007).

Claim Rejections - 35 USC § 103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21, 25, and 32 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6103759 (to Choi et al.) in view of U.S. Patent No. 5474990 (to Olney). This rejection is moot regarding claims 21, due to amendment, and 24 as it has been cancelled. The rejection is **maintained** over claims 1-20, 25, and 32 for the reasons of record and further below.

Response to Remarks:

Applicants first argue that the claims are now amended to exclude treatment of stroke

induced hypoxia/ischemia, and thus the rejections should be withdrawn. This is unpersuasive because the Choi et al. reference still teaches neurological conditions which fall within the elected species, i.e., hypoxic/ischemic injuries *not* caused by stroke.

As stated previously, Choi et al. teach the elected compound (see col. 8, Table I, entry 3). The cited table also teaches a dose of 50.0 mg/Kg. The reference also teaches that the compound can be used for the treatment of diseases of the central nervous system, particularly "convulsions, epilepsy, stroke and muscle spasm" (see. col. 7, lines 11-15).

Again, prior art references are to be considered in their entirety, are used for all that they teach, and are not limited to use of only preferred embodiments or Examples. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See MPEP 2141.02 and *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Therefore the invention as a whole is *prima facie* obvious.

2) Claims 1-21, 25, and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6103759 (to Choi et al.) in view of Zaidi et al. (*J Am Coll. Cardiol* 2000, Vol. 36(1), pages 181-184). This rejection is **maintained** for the reasons of record and further below.

Response to Remarks:

Applicants argue that the cerebrovascula syncope and resulting convulsions, from the Zaidi et al. reference, are no specifically related to neuronal dysfunction, And gives several other possible causes and effects of convulsions. This is not persuasive.

As stated previously, Choi et al. teach the elected compound (see col. 8, Table I, entry 3) and that the compound can be used for the treatment of diseases of the central nervous system, particularly "convulsions, epilepsy, stroke and muscle spasm" (see. col. 7, lines 11-15).

And while Choi et al. do not teach injury caused by hypoxia-ischemia, however Zaidi et al. teach many patients with cardiovascular syncope, described as abnormal movements due to **cerebral hypoxia**, experience convulsive blackouts (see abstract and p. 181). The reference also teaches that "complete arrest of cerebral circulation has been shown to be highly associated with convulsion" (p. 183, Discussion). Thus the combination of references do in fact teach a neurological disorder associated with an insult resulting from hypoxia. It should also be noted that the specification at page 2, bottom paragraph, teaches acute neuronal injuries resulting from hypoxia-ischemia related to cardiac conditions.

Thus treatment of the convulsions and epilepsy as administered in Choi et al. would also treat the accompanying hypoxia that occurs with the convulsions. It would have been obvious to one of skill in the art at the time the invention was made that since the convulsions and epilepsy accompany hypoxic-ischemic conditions and resulting injury, treatment with the instantly claimed compound would also treat hypoxia-ischemia occurring due to the convulsions. Therefore the invention as a whole is *prima facie* obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 25, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of acute neurodegenerative disorders associated with abrupt insult resulting from hypoxia-ischemia selected from cerebrovascular insufficiency, cerebral ischemia and cerebral infarction by administration of the compound of Formula (Ib) S-enantiomer, does not reasonably provide enablement for *prevention* of these acute neurodegenerative disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is **maintained** and modified for the reasons below.

Response to Remarks:

Applicants argue that "treatment" of a neurodegenerative condition "is preventing neuronal cell death...in a prophylactic manner preventing the disease condition from occurring in the first place." This is not persuasive. The definition of "treatment" includes prevention, which is precisely why the rejection was modified in the previous rejection, and is currently maintained.

In addition, Applicants argue that they have shown prevention as treatment in their examples. However, the examples are now drawn to an embodiment that has been specifically removed from the claims.

As stated previously, Applicant demonstrates *treatment* of transient cerebral ischemia in the rat MCAO model by administration of by administration of the compound of Formula (Ib) S-enantiomer (the elected compound). See Example 2, pages 20-22, which show significant reduction in infarct volume with administration of the elected species of compound. However, Applicants examples have not demonstrated ***prevention*** of neuronal cell death as a result of

treatment. Demonstration of *prevention* of the disease in a mammal would require more extensive evidence to demonstrate possession (See MPEP § 2164.03). It is well established in the courts that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor, See *In re Fisher*, 166 USPQ 18, at 24 and MPEP § 2164.04. *Additionally*, the specification states (in para. [0003]) that "prevention of neuronal cell death is required for the treatment of both acute and chronic neurodegenerative disorders". Thus, Applicant continues to define treatment as including prevention, which is not sufficiently described to enable a person skilled in the art to which is pertains to make or use the invention commensurate in scope with the claims without undue experimentation.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0518. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1613

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614